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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,727	01/17/2002	Graham D. Cook	1142.0125-00	2584

7590 03/23/2004

Finnegan, Henderson, Farabow,  
Garrett & Dunner, L.L.P.  
1300 I Street, N.W.  
Washington, DC 20005-3315

EXAMINER
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KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/046,727

**Applicant(s)**

COOK ET AL.

**Examiner**

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Action Summary**

Claims 1-3 and 7-9 of record rejected under 35 U.S.C. 102 (b) as being anticipated by Sunshine et al. (U.S. Patent No. 4,522,826) is maintained for the reasons stated in the previous office action.

Claims 4-6 and 10-13 of record rejected under 35 U.S.C. 103 (a) over Sunshine et al. (U.S. Patent No. 4,522,826) is maintained for the reasons stated in the previous office action.

### **Response to Arguments**

Applicants' arguments filed on January 20, 2004 have been fully considered but they are not persuasive. Applicants argue that Sunshine specifically fails to disclose the limitation of the claimed invention, where the composition is formulated to prevent negative interactions between ibuprofen and diphenhydramine. This is not persuasive because Sunshine teaches a composition comprising same active agents, same dosage amounts and same formulation (two-layer or bilayer). Accordingly, any prevention of negative interactions between ibuprofen and diphenhydramine would be inherent of cited reference. It is noted that Applicants' are claiming composition claims. As stated in *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)

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"discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known compositions. Applicants next argue that there is not teaching or suggestion in Sunshine, however, of an orally administrable composition which comprises both ibuprofen and diphenhydramine because Sunshine on column 10, table 2, only discusses administration of combinations of separate doses of ibuprofen and diphenhydramine to mice via gavage. This is not persuasive because it is clear that Sunshine teaches composition comprising both ibuprofen and diphenhydramine. Applicant' attention is drawn to title, abstract, column 3, lines 45-55, column 4, line 3, column 6, line 39, column 7, lines 10-13, lines 55-60, column 9, lines 65-68, column 10, lines 1-3, column 11, tables 3 and 4, and claim 39 and 40, where it clearly teaches pharmaceutical composition comprising diphenhydramine and ibuprofen or an oral administration. Applicants next argue that the bilayer tablets or caplets of the instant invention physically separate ibuprofen and diphenhydramine, thereby preventing any negative interactions between the two compounds and the problem associated with negative interactions between diphenhydramine hydrochloride and ibuprofen by using soft gelatin capsules containing these compounds in combination with polyethylene glycol, which is believed to protect against this interaction. This is not persuasive because Sunshine teaches that polyethylene glycol can be employed in the composition that can be formulated in two layers; therefore, it would inherently have the protection against the interaction of diphenhydramine hydrochloride and ibuprofen as claimed by the Applicants. Applicants' argument that the bilayer tablets or caplets of instant

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invention physically separate ibuprofen and diphenhydramine will not be addressed at this time since Applicants' claims are not drawn to the bilayer composition physically separate ibuprofen and diphenhydramine. Applicants argue that the negative interactions are especially pronounced when diphenhydramine HCl is combined with ibuprofen (see, page 12, lines 17-18, of the specification as filed), and the present invention solves the problem associated with negative interactions between diphenhydramine HCl and ibuprofen by using soft gelatin capsules containing these compounds in combination with polyethylene glycol, which is believed to prevent against this interaction. This is not persuasive because Sunshine et al. teaches the composition comprising very same active agents, same effective amounts formulated in very same formulation (two-layer) as claimed by the Applicants therefore, any prevention of the negative interactions or the effects would be inherent since they are the very same composition without side-by-side comparison. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of January 20, 2004 is deemed proper and asserted with full force and repeated to obviate applicants' claims.

None of the claims are allowed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

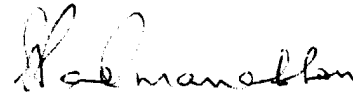
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan  
Supervisory Examiner  
Art Unit 1617

Jmk  
March 10, 2004